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Health care regulation in low-and middle-income countries: a review of the literature

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Health care regulation in low-and middle-income countries: a review of the literature.

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SUMMARY

Objectives: To review the published and grey literature on regulation theory and regulation of health care in low- and middle-income countries (LMICs).

Methods: Opportunistic literature search and review through electronic databases, review of grey literature and search of the worldwide web.

Results: Little empirical research has been conducted on the regulation of health care in LMICs. Most of the literature shows that regulation is centralised in state institutions, which may lack the capacity to monitor and enforce. Regulation needs to address increasingly commercialised health sectors. The costs of regulation need to be considered in relation to the observable benefits.

Conclusions: New ways of regulation that involve non-state actors and less bureaucratic ways of enforcing regulation need to be explored. De-centred regulation offers a different way of approaching regulation. This new approach can assist policy makers and development partners in the design of regulatory approaches in commercialised health care systems, with a focus on information exchange and quality standard control.

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INTRODUCTION

This paper discusses issues related to the regulation of health care in LMICs in the context of increasingly commercialised health care. Due to weak institutional capacity, state-centred approaches to regulation may be less effective in influencing the behaviour of individual health care providers and organisations. We introduce the concept of 'de-centred' regulation to describe some of the reasons for regulatory failures and offer direction for how regulatory systems can be reoriented in LMIC commercialised health sectors.

The growth of commercialised health care and the growing number of non-state actors in health care in LMICs are causing many countries to rethink the role of the state in the regulation of the commercial sector. Current approaches to regulation of health care in LMICs rely mostly on command and control strategies, administered mainly through state-centred institutions that are often not able to enforce regulation effectively (WHO 2000). Consequently, different regulatory approaches that are not exclusively state-centred may be required. Such approaches may involve non-state actors, civil society networks and other associations working in partnership to achieve health system goals of equity in access, efficiency, quality of service and public health protection.

This paper is based on a review of published literature on regulation theory and the regulation of health systems in LMICs and a documentary review of the grey literature. It begins with a discussion of context and methods, looking especially at contemporary health systems in which an increase in commercialised health care combines with a complex public-private mix of actors. This is followed by findings from a literature review, beginning with a discussion of common regulatory strategies, the main challenges to effective regulation and new approaches to regulation. The paper concludes with a discussion of findings and conclusions.

CONTEXT AND METHODS

Growth of Commercialised Health Care

Many LMICs are experiencing demographic and epidemiologic transitions that are placing greater demands on their health care systems. With increasing urbanisation, health care providers have typically concentrated their activities in and around cities, leaving rural areas under-supplied with basic services (Dussault and Franceschini 2006). Often related to this is the emergence of a new middle class that creates a demand for higher technology and hospital-based care (Bhat 1996).

Many countries are now encouraging the growth and development of the commercial sector to expand health care coverage and reduce the burden on the public health system. Mackintosh and Koivusalo (2005) define commercialisation of health systems as:

The provision of health care services through market relationships to those able to pay; investment in and production of those services and of inputs to them, for cash income or profit, including private contracting and supply of publicly financed health care; and health care finance derived from individual payments and private insurance.

Over the last two decades there has been growing interest in the role of non-state providers within health care systems (Mills, Brugha et al 2002). State-financed health care delivered through state services is perceived to be failing communities in many LMICs, where commercial providers can represent the majority of health care providers financed largely by out-of-pocket payments. This issue was previously identified by Berman (1998) and was raised more recently by Richard Feecham in a heated discussion with Hanson, Gilson et al (2008).

An important question within a context of expanding commercialised health care is how governments can be more effective in regulating to deliver on goals, including efficiency, effectiveness and equity. Regulation emerges as an important function in which state and non-state actors can negotiate roles and responsibilities and governments can direct the behaviour of market actors towards meeting health sector goals (WHO 2000).

Review of the Published and Grey Literature

This review of the literature was conducted in multiple ways. Textbooks were used to review regulation theory and practice. Five electronic databases were searched for published literature: Medline, Pubmed, Global Health, ELDIS and Web of Science. The world wide web was used to source grey literature on regulation theory and regulation in LMICs, with a focus on definitions of regulation, and reports on the commercial health sector.

The search of the published literature focused on health care regulation and commercialised health systems in both LMICs and developed countries, and health care markets in LMICs. For the selection of the published literature, the following inclusion criteria were applied:

- Is the paper based on an empirical study that analyses regulation in the health sector in LMICs?
- Does the paper discuss regulation related to health care markets, hospitals or medical professionals in LMICs?
- Does the paper provide evidence about the need for regulatory interventions in health systems in LMICs?

A total of 54 published titles were identified as meeting the above criteria, four being rejected as not sufficiently relevant for LMICs. Of the 50 papers selected, only five were empirical studies that examined regulation in LMICs.

The following questions were used as a framework for analysis:

- How is regulation defined?
- What are the problems of commercialised health sectors that regulation should address?
- What regulatory strategies are most commonly used?
- What are the main challenges for regulatory reforms in LMICs?
- What new approaches to regulation are helpful for analysing and guiding regulatory reform in LMICs?

COMMON REGULATORY STRATEGIES

The regulation of health care systems in LMICs is poorly documented, with little empirical research conducted into effective approaches (WHO 2010). Most of the literature on regulation derives from developed countries, which have a history of strong institutions, judicial systems, professional associations and civil society that are dynamically involved in implementing and monitoring regulation of health care. Similar conditions do not often prevail in LMICs, where health systems are typically decentralised and state institutions have limited capacity. In LMICs, both consumer influence and civil society participation are weaker, and non-state actors are rarely engaged in regulatory activities. Different approaches, which include decentralised low-cost and inclusive approaches to regulation, need to be sought in LMICs (Peters and Muraleedharan 2008).

Defining Regulation

There is no one agreed definition of regulation, and there are different opinions about the appropriate degree of government involvement in regulating social and economic activities. We summarise the various definitions in the literature into two categories: state-centred with a social focus; and state-centred with an economic focus. Social focus refers to equity and social justice, public protection, social cohesion and health and safety; economic focus refers to regulation of economic efficiency and setting rules for the health care market.

State-centred: social focus

Definitions presenting a social focus emphasise control, public authority and the power of the state; use regulatory instruments of a bureaucratic nature; and require a state authority to enforce regulations or influence behaviour. For example, Selznick groups regulation as a specific set of commands, a deliberate state of influence and all forms of social control or influence (Baldwin and Cave 1999). Social control is taken to include regulation in a way that emphasises social cohesion, equity, protection, controls and a social benefit as an aim. While the state is not explicitly mentioned in this definition, 'command' and 'deliberate state of influence' are usually understood to be state functions.

Walshe (2003) defines regulation as sustained and focused control exercised by a public agency over activities that are valued by a community. It is suggested that regulation is established as a continuous activity with a clear direction, firmly rooted in the public sector with public interest as the main purpose and where only public institutions are responsible for regulation.

Roberts, Hsiao et al (2004) identify the role of the state more explicitly as the core of regulation, exercised through the use of coercive power with the aim of changing individual and organisational behaviour in health care. Little scope is allowed for negotiation among different actors. The state is perceived as the dominant regulatory authority, regulatory instruments and legal tools are applied through the state. This strict definition likely reflects the history of regulation in the USA, where courts enforce regulation on the commercialised health system and health insurance industry. Historically, the health care system has controlled the power of the medical profession and its commercial aspirations and self-interest (Rodwin 2007; Sox 2007).

State-centred: economic focus

Another school of thought defines regulation in an economic context as government controlling or deliberately trying to influence the activities of actors by manipulating such variables as price, quantity and quality (Kumaranayake 1997). The responsibility rests firmly with state authorities, and it is assumed that manipulation of market rules for price, quantity and quality are sufficient to influence the behaviour of market actors and can lead to economic efficiency. Measurement of these variables would require considerable market behaviour and outcome data that are seldom available in LMICs. Attention has therefore tended to focus on quantity and quality controls among regulators in LMICs (Abatcha, Sall et al 2006).

Mackintosh (2008) focuses solely on the commercial sector and introduces the private health insurance industry. She defines regulation as 'actions by government bodies and government-appointed regulatory agencies to influence the provision of health services and health insurance by private providers through market sale'. Actions include price-setting rules, standards, competition policies, restrictions on the organisational forms of market actors and consumer rights licences. The government is perceived as the central driver behind regulation, selectively deploying and adjusting these actions.

The Challenge of Commercialised Health Systems

While commercial providers are an increasingly important source of health care for all socio-economic groups in LMICs, there is a growing body of evidence of negative effects on health outcomes from commercial service delivery within unregulated markets (Mackintosh 2008). Negative effects may be grouped into four main categories: quality control, information asymmetry, equity of access and consumer protection.

Commercial providers are a very diverse group, ranging from informal individual providers to highly sophisticated specialist hospitals (Bloom and Standing 2001; Mills, Brugha et al 2002; Hanson, Gilson et al 2008). As an illustration, Nandraj, Muraleedharan et al (2001) describe the range of commercial sector providers in India:

Allopathic treatment is the dominant care provided in both urban and rural settings. Most institutions are small urban nursing homes, with an average size of 10 beds, and are operated by doctor owners. The services provided range from simple treatment to sophisticated operations. The provision of private laboratory and diagnostic services, and blood banks are limited to urban and semi-urban areas. Another trend observed is a mushrooming growth of corporate hospitals in metropolitan cities. One of the interesting features revealed by the various studies is the wide variation in the type of providers available in India. They range from the unqualified person to the super specialised consultant, and from the temporary outpatient clinic or hospital having less than three beds, to the sophisticated multi-specialty corporate hospital with technology as current as any place in the world.

Controlling the number and distribution of health care facilities and quality of care and protecting consumers from opportunistic behaviour or malpractice is complex and require regulatory intervention. Of particular importance is the role of the informal sector, including informal pharmacies and drug retailers. The informal

sector is often the first point of contact for many poor persons in LMICs and generally fills the void left by a failing public sector (Hanson and Berman 1998; Bloom, Standing et al 2011).

Information asymmetry is identified as a major problem. Patients and consumers may be unaware of prices or unable to assess quality of care, and this can contribute to supplier-induced demand and increasing costs of health care (Bloom, Kanjilal et al 2008). For example, a study from India showed that private providers offered more diagnostic tests and hysterectomies than would normally be required by the symptoms. The same phenomenon has been reported in private hospitals in Peru, indicating supplier-induced demand (Peters 2002; Arrieta 2011).

The quality of care from private health care providers is a concern, with respect to harmful practices and poor technical quality, especially among informal or non-institutional providers (Patouillard, Goodman et al 2007; Bloom, Kanjilal et al 2008). Provision of medicines and medical care is seen as a business by providers, with increasing consumerist behaviour witnessed among purchasers. A study on health care regulation in Thailand revealed that 63 per cent of health expenditure in the greater Bangkok region was at private clinics and only 21 per cent was at public providers, indicating growing consumerist behaviour and highlighting the need for increased consumer protection systems due to possible over-servicing (Teerawattananon, Tangcharoensathien et al 2003).

Equity of access for the poor is also a primary concern. Qualified private providers are mostly not accessible or affordable by the poor, who rely on private informal providers that are largely unregulated (Bennett and Tangcharoensathien 1994; Purohit 2001; Bloom, Kanjilal et al 2008).

Current systems of regulation in LMICs are unable to control private health care systems. One reason for this is a lack of information or knowledge on the behaviour and activities of commercial, particularly informal, providers (Bloom, Kanjilal et al 2008). Furthermore, basic regulatory instruments, such as licensing and registration of facilities and providers, are often inadequate or poorly enforced. Accreditation systems to improve quality of care require the development of complicated regulatory instruments and technical and management capacity that is often lacking (WHO 2000; Nandraj, Khot et al 2001; Ensor and Weinzierl 2007).

Common Regulatory Strategies

Regulatory strategies are developed according to the purpose of regulation, which is typically defined by the social and economic objectives of health policy (Saltman, Busse et al 2002). Depending on these objectives, a mix of strategies can be used. Different regulatory strategies require different instruments to enforce regulations. Baldwin and Cave (1999) identify the most common regulatory strategies which we apply in the context of LMICs.

Command and control

LMICs commonly focus on this approach to regulation. State-centred legal instruments are used to enforce behaviour through bureaucratic processes. Examples of this are health and safety legislation and licensing and registration of doctors. Licensing of hospitals, pharmacies, laboratories and other health facilities requires that facilities meet specified standards of equipment and staffing before providing services.

Market-harnessing controls

Market-based strategies, such as competition or anti-trust laws, contracting, franchising and price controls, aim to manage market failure in health care. There is little documented evidence in the literature regarding economic regulation to control prices, provide consumer protection, set market rules or provide an economic framework within which health care markets can support policy objectives. Nevertheless, a number of examples are reported. In many LMICs, the contracting of providers using public financing is used as a way of increasing coverage of health services; suppliers can be private providers or NGOs, as well as public sector providers (Abatcha, Sall et al 2006). Franchising is also common practice in many LMICs, including India, Bangladesh and Pakistan. However, the evidence that franchising improves quality and pricing is mixed (Patouillard, Goodman et al 2007).

Self-regulation

Under this strategy, medical and associated health professional associations and medical colleges are themselves required to meet standards of education, professional development, quality control and professional conduct. Self-regulation allows peer groups within the industry to regulate the behaviour of health care organisations and of individual practitioners. An example of this is seen in Indonesia, where legislation has created the Indonesian Medical Council. It is responsible for professional codes of ethics, professional development of doctors and certification (Hort, Akhtar et al 2010). The council also has the authority to create its own regulations, which members are required to follow. However, not much evidence is available from LMICs on the effectiveness of professional associations in achieving objectives under self-regulation. Self-regulation has received much criticism on the basis that professional associations usually end up representing the self-interest of their members and become captured by members influencing regulation for their own benefit (Nunes, Rego et al 2007).

Incentive-based regimes

Under these regimes, tax incentives, financial and other incentives are used to influence the behaviour of providers and consumers. For example, incentive systems may be used to encourage practitioners to work in rural and under-served areas, or tax breaks may be given to hospitals to set up in under-served areas. Pay for performance is another financial incentive that has been introduced recently in LMICs; evidence suggests short-term objectives are achieved using pay-for-performance but long-term objectives are more difficult to sustain (Shiekh, Saligram et al 2011). Demand-side incentives, such as conditional cash transfers or vouchers to encourage the uptake of primary health care, are now being implemented in many Latin American countries and in Asia. These provide direct financial support to families for achieving specific targets such as attending antenatal care or delivery in a health facility with trained professionals (Lagarde, Haines et al 2009). Such market or economic-based incentives may be seen as alternatives to command and control, but they also require complex monitoring and information management systems, and their capacity requirements should not be underestimated.

Disclosure regulation

Disclosure regulation is designed to address information asymmetry. Health care organisations are required to provide open and transparent information to consumers and competitors on price, quality and quantity. The constraint is how consumers access and understand the information and what they do with it, particularly where there are limitations in literacy and education. While there is little documented evidence about the use of such regulatory strategies in LMICs, experience with disclosing information to communities in Tanzania and Sri Lanka seems to have been positive, showing that communities do make wise and sophisticated use of information (Ensor and Weinzierl 2007).

Direct action by government

Under this approach, the government takes direct action to meet policy and regulatory goals. In LMICs, governments are involved in direct provision of services to reach policy goals, and public service providers are regulated through bureaucratic and administrative instruments that measure performance. Richard Feecham believes the problem with this approach is the failure of governments to provide adequate quality, quantity and coverage for all (Hanson, Gilson et al 2008).

Social insurance

Health insurance markets can also act more broadly as a regulatory force. Governments are responsible for developing a legal framework that provides the rules for the insurance industry. Under insurance arrangements, payment for health care is generally made by third-party payers, which places conditions and controls on the consumers and providers. However, in low-income countries (LICs), health insurance markets are not well developed but are growing more rapidly in middle-income countries (MICs), where there are larger middle and wealthy classes.

The above summary of definitions and strategies for regulation of health care delivery provides an understanding of the regulatory environment in LMICs, illustrating who should conduct regulation and for what purpose. Our review of the literature also revealed the main challenges to effective regulation and what more innovative approaches may offer as ways to reorient regulatory systems to influence the behaviour of individual health care providers and health care organisations.

CHALLENGES TO EFFECTIVE REGULATION IN LMICs

A review of the literature identifies constraints on effective systems for regulation of the commercial health sector in LMICs, including poor enforcement, limited institutional capacity and cost-effectiveness of regulations.

Poor Enforcement

Poor enforcement of health regulations is reported as a primary problem (Ensor and Weinzierl 2007). The administrative burden of bureaucratic approaches to regulation can be considerable (Teerawattananon, Tangcharoensathien et al 2003). Regulation requires adequate monitoring and information systems, mechanisms for decision making about violations and guidelines on when and how to apply sanctions. For these reasons, failure to enforce regulations is usually attributed to lack of institutional capacity (WHO 2000).

The impact of competing priorities is also an important reason that regulation may not be enforced. An empirical study that examined the enforcement of pharmaceutical regulations in Laos revealed that the licensing of facilities had been introduced, but regulators had not developed sanctions in case of violations (Stenson, Syhakhang et al 2001). Moreover, due to lack of resources, trade-offs had to be made with the geographical distribution of pharmacies and enforcing of quality regulation.

Variations in Institutional Capacity

Regulation and enforcement are dependent on institutional capacity, which is generally weaker in LICs than in MICs (WHO 2000). MICs may have a much larger commercial health sector as well as more resources to channel into regulation. Findings from regulation studies in Zimbabwe and Tanzania (Hongoro and Kumaranayake 2000; Kumaranayake, Lake et al 2000), Laos (Stenson, Tomson et al 1997) and Thailand (Teerawattananon, Tangcharoensathien et al 2003) illustrate these differences. In Thailand, roles and responsibilities of regulators, and regulations that covered both public and private sectors, were found to be comprehensive. Administrative structures, rules, incentives and standards were in place, indicating that Thailand has reached a stage of institutional development and capacity that can produce these regulatory systems. But the LICs had not made these achievements, mostly due to the lack of institutional development and the limited availability of resources.

Compared to MICs, in LICs there are more international actors—including non-government organisations, UN agencies and bilateral donors—those provides resources and exert influence on health policy, strategy and implementation (Palmer 2006). All actors need to be involved in regulation.

The distinction between LMICs—or, put differently, the distinction between countries with low or virtually non-existent institutional capacity and those with more developed institutional capacity—determines the capacity level at which analysis for regulatory reform begins. In addition, LICs may be able to learn from the experiences of MICs. Experience shows that if regulatory frameworks are adopted at the right time, the worst problems may be avoided or at least managed, but once the private sector has grown large, it is difficult to introduce regulation (Kumaranayake 1997; Mills, Brugha et al 2002).

Cost of Enforcement

Another reason for poor regulation may be the cost of enforcement compared to its perceived benefits (Ensor and Weinzierl 2007). This is an important consideration for policy makers and regulators, especially in resource-poor countries. Cost of regulation includes the cost of data collection, inspection and monitoring. Regulation requires skilled personnel and dedicated departments or units, appropriately equipped to enforce rules. The cost-benefit and cost-effectiveness of regulation have been interpreted by Ensor and colleague under four

categories (Ensor and Weinzierl 2007):

- efficient and effective: cost to regulate is less than social costs and achieves compliance;
- efficient but ineffective: cost to regulate is insufficient to achieve compliance;
- effective but inefficient: achieves compliance but at higher than acceptable social cost;
- ineffective and inefficient: costs are too high and system does not achieve compliance.

Ambitious regulatory efforts can also fall short due to the lack of resources to implement them. A survey of 1157 respondents in India measured attitudes of public sector managers and private hospitals to the introduction of accreditation as a quality control measure. The proposal received widespread support from both public sector regulators and private hospitals. The main obstacle to implementation was lack of resources to finance the accreditation system (Nandraj, Khot et al 2001).

Nature of the Commercial Sector

In LMICs, regulation generally focuses on formal-sector commercial providers through licensing of health professionals, pharmaceuticals, medical technologies and health facilities. Defining standards for performance, such as through the accreditation of hospitals, is a more common practice but is commonly voluntary (Ensor and Weinzierl 2007). Regulation becomes a pressing need if the behaviour of commercial sector providers is seen to be undermining, or in contradiction with national health goals.

Data collection and the information on commercial providers necessary for effective regulation are typically limited in LMICs. There is often poor awareness of existing regulation among commercial providers, and communication of regulatory requirements is often limited (Stenson, Tomson et al 1997; Hongoro and Kumaranayake 2000). There is little evidence of involvement of commercial sector organisations or representatives of professional associations in regulatory processes. While there is a common view that the commercial sector provides a better quality of health care, the evidence on this remains unclear, and significant problems with quality, opportunistic behaviour and malpractice in the commercial sector have been observed (Patouillard, Goodman et al 2007; Bloom, Kanjilal et al 2008).

Price Control and Competition

Economic regulation seeks to control variables such as price, quantity, quality and competition in market transactions. There are few examples in the literature of price control or effective policies to manage competition between commercial providers or to develop consumer protection laws. India has introduced such an act (Consumer Protection Act 1986), but this has been poorly implemented, with little response to complaints by consumers against health care providers (Bhat 1999).

Role of Medical Professionals

Historically, medical professionals and their associations have been self-regulating (Jacobson 2001). In LMICs, medical professionals commonly dominate ministries of health and may themselves be responsible for the design of health policy and health care regulation.

The regulation of the medical profession is difficult and generally requires self-regulation through the involvement of medical associations (WHO 2000). The main regulatory instruments used by Ministries of Health (MOH) are licensing and registration of professionals. The quality of education, training and continued professional development of doctors is poorly monitored and generally delegated to professional associations. Nevertheless, medical associations can play an important role in controlling standards and quality, implementing professional standards, codes of conduct, medical ethics, accreditation and continued professional development, all of which can influence the behaviour and quality of providers.

In the United States, there is a close relationship between business, the state and the medical profession. Where physicians practise as medical entrepreneurs and consequently seek primarily to maximise their revenues, a conflict of interest arises, and key regulatory concerns emerge in regard to meeting the medical needs of patients (Rodwin 2007; Sox 2007). While this may also occur in LMICs, the literature provides little help on how to manage the problem.

Dual Practice

The combination of poor government salaries and the growth of the commercial sector have increased the movement of medical and allied health professionals into private hospital facilities and clinics (WHO 2000). Private providers therefore increasingly compete with the public sector for both human resources and patients, and in many countries the same providers move between public and private practice. Private practice among public sector health workers ranges from 14 per cent in Thailand to 70 per cent in Zimbabwe (Kiwanuka, Kinengyere et al 2011). This has an impact on equity, efficiency and availability of services in public facilities (Dussault 2008). The impact of dual practice depends on the regulatory framework. The regulation of health professionals is an important focus of state regulation in most countries but a complex phenomenon that has both positive and negative effects (Jan, Bian et al 2005; Eggleston and Bir 2006).

NEW APPROACHES TO REGULATION

Understanding the above difficulties and challenges to health care regulation in LMICs leads us to consider alternative approaches that may be more appropriate and more effective. Recent approaches involving responsive and de-centred regulation may provide a means for more effectively addressing regulation issues and contribute to more equitable outcomes.

Responsive Regulation

Responsive regulation attempts to move beyond the ideological debate that views market and government relations as a dichotomy (Ayers and Braithwaite 1992). The responsive regulation approach is based on an understanding that the best regulatory strategies depend on context, regulatory culture and history. It accepts that, with the emergence of new actors in regulation and policy, command and control models of regulation and single regulatory instruments are seldom effective, and different approaches are needed (Healey and Braithwaite 2006).

Supporters of this approach propose a pyramid of actions that can be taken by regulators. Actions start with a soft approach, such as voluntary actions using guidelines, introducing principles or continuing education as guidance. Regulators can then employ other measures, such as market mechanisms, followed by self-regulation. If compliance is not achieved, then regulators use harder instruments of enforced self-regulation and consumer protection agents, until finally a command-and-control mechanism is invoked. Severe actions are taken such as revoking a hospital licence or banning an individual from practising (Braithwaite, Healey et al 2005).

Responsive regulation includes a number of the regulatory strategies mentioned by Baldwin and Cave (1999): command and control, self-regulation, market mechanisms. The main difference is that responsive regulation provides a hierarchy of actions and tools. The approach is not without its critics. For example, Walshe argues that responsive regulation appears an appealing and sensible approach but there is little empirical evidence that it is effective and it is difficult to test. Furthermore, it is argued that most regulators in health care do not behave according to the principles of responsive regulation (Walshe 2003).

De-Centred Regulation

De-centred regulation involves a shift away from the state as the sole regulator. It expands regulatory activities to actors and measures beyond the state and 'de-limits' regulation as an act of control to a range of activities and mechanisms that can influence the behaviour of actors. The concept of de-centred regulation was developed by Black (2002), who proposed the following definition:

Regulation is a sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing broadly identified outcomes or outcome, which may involve mechanisms of standard setting, information gathering and behaviour modification.

Proponents of de-centred regulation identify five main reasons why traditional regulation systems fail.

Collapse of the public-private distinction

This presents a real challenge for regulation because it calls into question the role of formal authorities. Within an overlapping public-private system, hybrid organisations and networks combine governmental and non-governmental actors in different ways. In this environment, regulation becomes a product of activity conducted by these mixed systems.

Fragmentation

Fragmentation of knowledge, power and control goes further than mere information asymmetry. No single actor can ever have the knowledge or information required to solve complex problems. Therefore, no single actor can employ the instruments necessary to regulate. Fragmentation of power means that different actors hold different levels and degrees of power, and government does not have a monopoly on power. Rather, power is dispersed among social and economic actors and the state.

Complexity

The health system is complex. The process of interaction between the various components and actors is dynamic and imperfectly understood. Actors have diverse goals, norms and power, and they harbour their own intentions.

Autonomy and ungovernability of regulatory actors or systems

Actors will continue to behave as they wish in the absence of intervention. Actors and systems are therefore often self-regulating. Interventions will have good and bad unintended effects, and no single actor can dominate the regulatory process because of the autonomy of other actors. Furthermore, actors and systems do have the capacity to regulate themselves, and this capacity should be harnessed to be effective.

Interactions and interdependencies

Because of the interdependencies between regulators and those regulated, there can be two-, three- or four-way processes that co-produce regulation. These processes can go beyond national borders to regional and international levels.

The de-centred approach to analysing regulation allows for non-state actors, networks and associations to interact in dual roles as regulators and the regulated. They are involved in co-producing regulation that may not be bureaucratic instruments aimed at control over economic and social activities but ways of organising and exchanging information to influence behaviour and regulatory outcomes. De-centred regulation therefore becomes a strategic approach that can be used by the state to implement a range of regulatory strategies, but it does not need to be the sole agent producing regulations, detecting deviations and violations and enforcing rules.

DISCUSSION AND CONCLUSION

The emergence of hybrid public-private and increasingly commercialised health systems in LMICs requires a new level of thinking about regulatory approaches. A common view is that centralised control through the state is ineffective in regulating the commercial health sector. A de-centred approach may show how regulation of health care in LMICs can be more effective.

A de-centred approach requires commercial health providers and representatives to consult with civil society networks or consumer groups involved in co-regulation. This co-regulation could assist with tackling information gaps, fragmentation and ungovernability by accepting the interdependencies and the collapse of the public-private distinction. The emphasis on co-regulation could lead to more negotiated agreement on roles and responsibilities between state and non-state actors.

The de-centred process would focus on a mix of regulatory strategies, such as market approaches, information disclosure, information exchange, standard setting and consumer protection. From these strategies, information exchange systems and standard setting should be given priority because reliable information systems that capture the behaviour of market actors are often one of the most costly and complex activities for the state.

These types of activities would define a different role and capacity for state authorities than is currently seen in many LMICs, requiring engagement and collaborative forums.

Standard setting is linked to public protection and information exchange but requires deeper involvement of professional and specialist networks. While standard setting systems exist in many countries, including medical education standards, nursing standards and medical associations setting standards of clinical care, these have often been poorly monitored. The issue is how to make these standards work through the commercial sector and modify behaviour, particularly in the informal sector.

Coordination of the informal sector is difficult and, without incentives or collaborative forums, is unlikely to attract the involvement of informal providers. Incentive approaches come in different forms; the example of accreditation in Mumbai, India, showed that a commercial hospital seized the opportunity to become more competitive by becoming accredited, which sent a signal of quality to consumers. In this case, the lack of financing was the obstacle. But this is where the state can step in and support an enabling environment with collaboration from the commercial sector.

Differences between LICs need to be considered. With lower institutional capacity, LICs often require support from development partners to develop regulatory frameworks. There is a growing interest and promotion of market-based approaches to the scaling up of health care and products for the poor, with international organisations such as the International Finance Corporation, World Bank, USAID, non-government organisations and donors all seeking ways of harnessing the commercial health sector in LMICs. However, efforts to assist country partners in the development of regulatory frameworks and techniques are lagging. The reasons for this are not well documented, but may be due to the limited evidence of effective approaches. As well, there is a lack of investment in institutional capacity and seeking different ways of achieving regulatory outcomes. Consequently, international actors actively promoting commercialisation of the health sector should also provide investment for improved regulatory systems.

The timing of the implementation of regulatory frameworks needs to be closely matched with the growth of the commercial sector. MICs which have substantial commercial sectors, may face more barriers to regulation due to the size and fragmentation of the sector. There may be many vested interests resisting regulatory advancements. LICs on the other hand, may still be in a position to build regulatory capacity and systems that can appropriately control growing commercialised health systems before they reach the size of the commercial sector in MICs.

Experience from developed countries shows that regulation involves state and non-state institutions working together, and that consumer groups and consumer information systems are in place. Actors are involved in dynamic processes that are always changing as the regulatory environment changes, but these conditions are far from the reality in LMICs.

The consequences of unregulated health care markets in LMICs are potentially serious, including increasing inequities, further weakening of public sectors, opportunistic behaviour and poor quality care. Such circumstances undermine health objectives and can harm the weakest and most vulnerable members of society. Regulation of health care in LMICs should always maintain a culture of public interest and protection.

There exists little empirical research on regulation of health care in LMICs. Further research needs to provide evidence on low cost, de-centred approaches that involve a mix of regulatory strategies by state, non-state and civil society actors, as well as an understanding of the institutions and dynamics of existing regulatory systems in LMICs. The growth of commercialised providers and dual practice is driving much of the change in contemporary LMIC health systems. More innovative approaches to regulation are needed that work effectively across both public and private segments. The de-centred approach of engaging with non-state sectors, using information exchange systems and standard setting can provide a useful way of thinking through regulatory reforms.

HP-100 P11
14884

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